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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/060,409	04/14/1998	DINAH W. Y. SAH	860098.420	9564

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EXAMINER
FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
1632	34

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary	Application No.	Applicant(s)	
	09/060,409	SAH ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-16 and 47-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *6-10,47 and 48* is/are allowed.

6)☒ Claim(s) *11-16,49 and 52-78* is/are rejected.

7)☒ Claim(s) *50 and 51* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed September 9, 2002 (Paper No. 33, initially filed unsigned June 17, 2002) has been entered. Claims 10, 12, 15, 16, 53-55 and 62-69 have been amended. Claims 70-77 have been newly added.

Accordingly, Claims 6-16 and 47-78 are pending in the instant application.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 17, 2002 (Paper No. 32) has been entered.

Claim Rejections - 35 USC § 112

Claims 54-69 stand rejected and Claims 12, 13-16, 49, 52, and 70-78 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record advanced on pages 2-4 of the Office Action of Paper No. 19 (mailed 6/5/01), as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 12, 13-16, 49, and 52 are directed to conditionally-immortalized dorsal root ganglion progenitor cells and neurons.

Claims 54-59 and 70-73 are directed to methods for transplanting cells into a mammal or patient.

Claims 60, 61, and 74 are directed to a method for screening for an agent that modulates the activity of a protein produced by a dorsal root ganglion cell. Claims 62, 63, and 75 are directed to a method for detecting the presence or absence of a protein in a sample. Claims 64, 65, and 76 are directed to a method of identifying a human dorsal root ganglion gene or protein. Claims 66, 67, and 77 are directed to a method for screening for an agent that affects dorsal root ganglion cell death. Claims 68, 69, and 78 are directed to a method for screening for a protein that regulates dorsal root ganglion cell death.

At page 10, paragraph 3 of the response, Applicants argue that since claims 54 and 55 do not recite therapeutic efficacy and methods of transplanting cells are known, these claims are enabled. However, the only utility asserted in the specification for transplanting the cells is to provide a therapeutic benefit. Thus, enablement is evaluated for the only asserted utility. Applicants suggest that the method of transplantation is a research tool. However, such a method does not rise to the level of a research tool, rather it would constitute further research in the development of protocols for therapeutic transplantation.

At page 10, paragraph 5 of the response, Applicants argue that the specification is enabling for the methods for screening for an agent that modulates the activity of a protein produced by a dorsal root ganglion cell because the specification refers to techniques that are well-known in the art. Furthermore, the Federal Circuit has stated that:

> a specification need not disclose what is well known in the art. See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, **when there is no disclosure** of any specific starting material **or of any of the conditions under which a process can be carried out, undue experimentation is required; there**

> **is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.** It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1005 (CAFC 1997) (emphasis added).

In the instant case, Applicants argue that the art itself provides the parameters to measure to determine whether a specific compound modulates the activity of a protein produced by a dorsal root ganglion cell. However, it is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 60-63, and 66-69 stand rejected and Claims 74, 75, 77, and 78 are rejected under 35 U.S.C. 112, second paragraph, for reasons of record advanced on pages 5-7 of the Office Action of Paper No. 19 (mailed 6/5/01),, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 60, 61, and 74 are indefinite in their recitation of "measuring the ability of the candidate agent to modulate the activity of a protein produced by the cell" because it is unclear what type of measurement is being referred to.

Claims 62, 63, and 75 are indefinite in their recitation of "detecting a response or lack of response in the cell" because it is unclear what type of response is to be detected. The claims are also indefinite in their recitation of "wherein said response is correlated with the presence of said protein" because it is unclear how the "response" correlates with the presence of the protein in the sample.

Claims 66, 67, and 77 are indefinite in their recitation of "measuring the ability of the candidate agent to affect death of the cell by measuring cell death" because it is unclear what type of measurements

are to be made to measure cell death. Furthermore, it is unclear how the measurement correlates with "identifying an agent that affects dorsal root ganglion cell death."

Claims 68, 69, and 78 are indefinite in their recitation of "measuring the effect of the alteration on the death of the cell by measuring cell death" because it is unclear what type of measurements are to be made to measure cell death.

The rejection of Claims 49 and 52 under 35 U.S.C. 102(e) is withdrawn in view of Applicants arguments.

Conclusion

Claims 6-10, 47, and 48 are allowable.

Claims 50 and 51 are objected to as being dependent on a rejected base claim, but would be allowable if re-written in independent form including all the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Tiffiany Tabb, whose telephone number is (703) 305-1238.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE BAKER
PATENT EXAMINER